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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,170	09/18/2003	Jaime Vargas	144	6321

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CARDICA, INC.
900 SAGINAW DRIVE
REDWOOD CITY, CA 94063

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/665,170	Applicant(s) VARGAS ET AL.	
	Examiner Julian W. Woo	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/21/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 21, 2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 14, 15, 21, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Yencho et al. (6,461,320). Yencho et al. disclose, at least in figures 24 and 28D and in col. 13, lines 3-14; a method of forming an anastomosis, where the method includes providing a unitary, partially tubular anastomosis device (110), connecting or everting an end of a graft vessel (125) around the anastomosis device,

delivering at least a portion of the device into a lumen of a target vessel (127) through an opening in the wall of the target vessel, manipulating, radially expanding, or plastically deforming at least a portion of the anastomosis device with an expander (131) to form a first flange (121) positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel, where manipulating includes completely forming the first flange (within the lumen of the target vessel) and moving it into contact with the wall of the target vessel after the manipulating is complete, where manipulating the anastomosis device includes translating the expander relative to the anastomosis device at joining of the anastomosis device to the expander, and where translating comprises translating the distal end of the expander (at 136 as seen in figure 24) from a position within the anastomosis device to position distal to and outside of the anastomosis device.

4. Claims 1, 7-13, 16-20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al. (6,113,612). Swanson et al. disclose, at least in figures 2, 3, 7-11, and 15-19 and in col. 4, lines 54-59; col. 7, line 47 to col. 8, line12; and col. 9, lines 23-67; a method of forming an anastomosis, where the method includes providing a stainless steel anastomosis device (10), connecting an end of a graft vessel (120) to the anastomosis device, delivering at least a portion of the device into a lumen of a target vessel (300) through an opening in the wall of the target vessel; manipulating an expander (110) relative to the device in order to form a first flange (40) with a plurality of radially arranged elements positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel (see fig. 10, where at least the distal portion of

the graft separates the wall of the target vessel from the first flange), where manipulating completely forms the first flange (at inflation of the expander and before contact of element 42 with the target vessel), where the first flange is further moved substantially linearly into contact with the wall of the target vessel (at 42) after completion of the manipulating, where the method includes providing and connecting a separable holder (220) to the device, and moving the holder (220), where the device includes at least one tab (22) at its proximal end for connecting to the holder (see fig. 7), where manipulating the device includes forming a second flange (20) proximal to the first flange and positioned outside and in contact with the target vessel (see fig. 11), where the graft vessel is penetrated with elements 22; where manipulating the device includes moving a portion of one element away from a portion of a different (e.g. opposing) element, and where translating (see at least fig. 7) comprises translating the distal end of the expander (110) from a position within the anastomosis device to a position distal to and outside of the anastomosis device (during the joining of the anastomosis device to the expander).

Additionally, Swanson et al. disclose the method of claim 1 with anastomosis device 410 (see figs. 15-19), where manipulating of the anastomosis device includes completely forming of a first flange (460, 462, or 464) with an expander (a "dual balloon system" or a "single 'bulbous' shaped balloon") prior to moving the first flange into contact with a target vessel.

Response to Amendment

5. Applicant's arguments filed on December 21, 2006 have been fully considered but they are not persuasive: See the restatement of the rejection above. That is, Yencho et al. and Swanson et al. indeed disclose, that at manipulation of the anastomosis device, a first flange is formed within a target vessel lumen prior to movement of the first flange into contact with the wall of the target vessel.

Conclusion

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

February 22, 2007